

Practitioner's Docket No.

2960/112

PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Lang et al.

Application No.: 10/681,749

Group No.: 3738

Filed: October 7, 2003

For: Minimally Invasive Joint Implant with 3-Dimensional Geometry Matching The Articular Surfaces

Mail Stop Amendment

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

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BEFORE MAILING OF FIRST OFFICE ACTION (37 C.F.R. § 1.97(b))IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING  
INFORMATION DISCLOSURE STATEMENT

The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. § 1.97(b).

## CERTIFICATION UNDER 37 C.F.R. §§ 1.8(a) and 1.10\*

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37 C.F.R. § 1.8(a)

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37 C.F.R. § 1.10\*

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Date: July 21, 2005

Alexander J. Smolenski, Jr., Esq.

(type or print name of person certifying)

\* Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

DATE: July 21, 2005



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US

02960/112 417522

Practitioner's Docket No. 2960/112 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent application  
of \_\_\_\_\_

Inventor(s) \_\_\_\_\_

for \_\_\_\_\_  
Title of invention \_\_\_\_\_

the specification of which is being transmitted herewith

OR

In re application of: Lang et al.

Application No.: 10/681,749

Group No.: 3738

Filed: October 7, 2003

Examiner: Not yet assigned

For: **Minimally Invasive Joint Implant with 3-Dimensional Geometry Matching The Articular Surfaces**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

(Information Disclosure Statement--page 1 of 13)

**CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10\***

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**37 C.F.R. SECTION 1.8(a)**

**37 C.F.R. SECTION 1.10\***

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Alexander J. Smolenski, Jr., Esq.

Date: July 21, 2005

**\*WARNING:** Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. section 1.10(b).

"Since the filing of correspondence under section 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable C.F.R.e, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

**NOTE:** "An information disclosure statement shall be considered by the Office if filed by the applicant:

- (1) Within three months of the filing date of a national application;
- (2) Within three months of the date of entry of the national stage as set forth in section 1.491 in an international application; or
- (3) Before the mailing date of a first Office action on the merits, whichever event occurs last." 37 C.F.R. section 1.97(b).

**NOTE:** "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. section 1.56(a).

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;
- (2) each attorney or agent who prepares or prosecutes the application; and
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. section 1.56(c).

**NOTE:** The "duty as described in section 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by sections 1.97(b) - (d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O.G. 13-25 at 17.

**WARNING:** "No information disclosure statement may be filed in a provisional application." 37 C.F.R. section 1.51(b).

### **List of Sections Forming Part of This Supplemental Information Disclosure Statement**

The following sections are being submitted for this Information Disclosure Statement:

(check sections forming a part of this statement: discard unused sections and number pages consecutively)

1. ☒ Preliminary Statements
2. ☒ Forms PTO/SB/08A and 08B (substitute for Form PTO-1449)
3. ☐ Statement as to Information Not Found in Patents or Publications
4. ☐ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
5. ☐ Cumulative Patents or Publications
6. ☒ Copies of Listed Information Items Accompanying This Statement
7. ☐ Concise Explanation of Non-English Language Listed Information Items
  - 7A. ☐ EPO Search Report
  - 7B. ☐ English Language Version of EPO Search Report
8. ☐ Translation(s) of Non-English Language Documents
9. ☐ Concise Explanation of English Language Listed Information Items (Optional)
10. ☒ Identification of Person(s) Making This Information Disclosure Statement

(complete the following, if appropriate)

Sections \_\_\_\_\_, respectively, have been continued on ADDED PAGE(S).

**NOTE :** "Once the minimum requirements are met, the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).

## **Section 1. Preliminary statements**

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. section 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

**SECTION 2. FORMS PTO/SB/08A and 08B (formerly Form PTO-1449)**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Lang et al. Attorney Docket: 2960/112  
Serial No: 10/681,749 Art Group Unit: 3738  
Date Filed: October 7, 2003 Examiner Name: Not yet assigned  
Invention: Minimally Invasive Join Implant with 3-Dimensional Geometry Matching the Articular Surfaces

**LIST OF PATENTS AND PUBLICATIONS FOR  
APPLICANT'S SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

U.S. PATENT DOCUMENTS					
Examiner Initials	Reference Number	Document Number	Issue Date/ Publication Date	Inventor	Class/Subclass
	AA	US 4,055,862	Nov. 1997	Farling	3/1.91
	AB	US 4,203,444	May 1986	Bonnell et al.	128/176
	AC	US 4,586,496	May 1986	Keller	128/92
	AD	US 4,601,290	Jul. 1986	Effron et al.	128/305
	AE	US 4,609,551	Sep. 1986	Caplan et al.	424/95
	AF	US 4,627,853	Dec. 1986	Campbell et al.	623/16
	AG	US 4,846,835	Jul. 1989	Grande	623/11
	AH	US 5,041,138	Aug. 1991	Vacanti et al.	623/16
	AI	US 5,067,964	Nov. 1991	Richmond et al.	623/18
	AJ	US 5,197,985	Mar. 1993	Caplan et al.	623/549
	AK	US 5,206,023	Apr. 1993	Hunziker	424/423
	AL	US 5,226,914	Jul. 1993	Caplan et al.	623/549
	AM	US 5,270,300	Dec. 1993	Hunziker	514/12
	AN	US 5,306,311	Apr. 1994	Stone et al.	623/18
	AO	US 5,368,858	Nov. 1994	Hunziker	424/423
	AP	US 5,468,787	Nov. 1995	Braden et al.	523/113
	AQ	US 5,632,745	May 1997	Schwartz	606/75
	AR	US 5,671,741	Sep. 1997	Lang et al.	128/653.2
	AS	US 5,728,162	Mar. 1998	Eckhoff	623/20
	AT	US 5,749,874	May 1998	Schwartz	606/75
	AU	US 5,769,899	Jun. 1998	Schwartz et al.	623/18
	AV	US 5,876,217	Jul. 1998	Tubo et al.	435/402
	AW	US 5,827,289	Oct. 1998	Reiley et al.	606/86
	AX	US 5,842,477	Dec. 1998	Naughton et al.	128/898
	AY	US 5,853,746	Dec. 1998	Hunziker	424/426
	AZ	US 5,871,018	Feb. 1999	Delp et al.	128/898
	BA	US 5,900,245	May 1999	Sawhney et al.	424/426

U.S. Patents (cont.)					
Examiner Initials	Reference Number	Document Number	Issue Date/ Publication Date	Inventor	Class/Subclass
	BB	US 5,906,934	May 1999	Grande et al.	435/325
	BC	US 5,939,323	Aug. 1999	Valentini et al.	435/395
	BD	US 5,972,385	Oct. 1999	Liu et al.	424/486
	BE	US 6,082,364	Jul. 2000	Balian et al.	128/898
	BF	US 6,110,209	Aug. 2000	Stone	623/16.11
	BG	US 6,120,541	Sep. 2000	Johnson	623/14.12
	BH	US 6,126,690	Oct. 2000	Ateshian et al.	623/18
	BI	US 6,139,578	Oct. 1000	Lee et al.	623/16.11
	BJ	US 6,200,606	Mar. 2001	Peterson et al.	424/574
	BK	US 6,203,576	Mar. 2001	Afriat et al.	623/20.27
	BL	US 6,214,369	Apr. 2001	Grande et al.	424/423
	BM	US 6,217,894	Apr. 2001	Sawhney et al.	424/426
	BN	US 6,219,571	Apr. 2001	Hargreaves et al.	600/410
	BO	US 6,251,143	Jun. 2001	Schwartz et al.	623/23.72
	BP	US 6,277,151	Aug. 2001	Lee et al.	623/23.61
	BQ	US 6,281,195	Aug. 2001	Rueger et al.	514.21
	BR	US 6,283,980	Sep. 2001	Vibe-Hansen et al.	606/151
	BS	US 6,299,905	Oct. 2001	Peterson et al.	424/486
	BT	US 6,328,765	Dec. 2001	Hardwick et al.	623/23.72
	BU	US 6,344,059	Feb. 2002	Krakovits et al.	623/20.31
	BV	US 6,351,558	Mar. 2002	Spector	623/18.11
	BW	US 6,358,253	Mar. 2002	Torrie et al.	606/96
	BX	US 6,371,958	Apr. 2002	Overaker	606/72
	BY	US 6,375,658	Apr. 2002	Hangody et al.	623/20.18
	BZ	US 6,379,367	Apr. 2002	Vibe-Hansen et al.	606/151
	CA	US 6,383,228	May 2002	Schmotzer	623/23.35
	CB	US 6,429,013	Aug. 2002	Halvorsen et al.	435/377
	CC	US 6,443,988	Sep. 2002	Felt et al.	623/17.12
	CD	US 6,444,222	Sep. 2002	Asculai et al.	424/484
	CE	US 6,459,948	Oct. 2002	Ateshian et al.	700/117
	CF	US 6,468,314	Oct. 2002	Schwartz et al.	623/23.72
	CG	US 6,479,996	Nov. 2002	Hoogeveen et al.	324/309
	CH	US 6,520,964	Feb. 2003	Tallarida et al.	606/71
	CI	US 6,632,235	Oct. 2003	Weikel et al.	606/192
	CJ	US 6,652,587	Nov. 2003	Felt et al.	623/20.16
	CK	US 6,679,917	Jan. 2004	EK	600/587

U.S. PUBLISHED APPLICATIONS					
Examiner Initials	Reference Number	Document Number	Issue Date /Publication Date	Inventor	Class/ Subclass
	CL	2001/0010023	Jul. 2001	Schwartz et al.	623/23.72
	CM	2001/0039455	Nov. 2001	Simon et al.	623/23.51
	CN	2002/0013626	Jan. 2002	Geistlich et al.	623/23.57

**U.S. PUBLISHED APPLICATIONS (cont.)**

Examiner Initials	Reference Number	Document Number	Issue Date /Publication Date	Inventor	Class/ Subclass
	CO	2002/0045940	Apr. 2002	Giannetti et al.	623/11.11
	CP	2002/0059049	May 2002	Bradbury et al.	703/11
	CQ	2002/0087274	Jul. 2002	Alexander et al.	702/19
	CR	2002/0106625	Aug. 2002	Hung et al.	435/1.1
	CS	2002/0183850	Dec. 2002	Felt et al.	623/20.16
	CT	2002/0087274	Jul. 2002	Alexander et al.	702/19
	CU	2002/0115647	Aug. 2002	Halvorsen et al.	514/171
	CV	2002/0120274	Aug. 2002	Overaker et al.	606/72
	CW	2002/0120281	Aug. 2002	Overaker	606/151
	CX	2002/0151986	Oct. 2002	Asculai et al.	424/484
	CY	2002/0156150	Oct. 2002	Asculai et al.	623/23.75
	CZ	2003/0216669	Nov. 2003	Lang et al.	600/587
	DA	2005/0043807	Feb. 2005	Wood	623/20.14

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Reference Number	Country Code	Document Number	Publication Date	Patentee or Applicant	Class/Subclass
	DB	EP	0528080	Aug. 1991	Richmond et al.	A61F 2/30
	DC	EP	0626156	Jan. 1992	Walker	A61F 2/38
	DD	EP	0530804	Sep. 1992	Hunziker	A61L 25/00
	DE	EP	0613380	Nov. 1992	Braden et al.	A61L 27/00
	DF	EP	0814731	Jan. 1996	Schwartz et al.	A61F 2/30
	DG	EP	0833620	Jun. 1996	Yayon et al.	A61K 9/22
	DH	EP	0896825	Aug. 1997	Atkinson et al.	A61L 27/00
	DI	EP	1077253	Aug. 2000	Halvorsen et al.	C12N 5/00
	DJ	EP	1120087	Jan. 2001	Schwartz et al.	A61B 17/06
	DK	EP	1129675	Mar. 2001	Overaker	A61F 2/30
	DL	EP	1234552	Feb. 2002	Overaker	A61F 2/00
	DM	EP	1234555	Feb. 2002	Overaker	A61F 2/30
	DN	WO	93/04710	Mar. 1993	Hunziker	A61L 25/00
	DO	WO	93/09819	May 1993	Braden et al.	A61L 27/00
	DP	WO	93/25157	Dec. 1993	Rau et al.	A61B 17/57
	DQ	WO	96/24302	Aug. 1996	Schwartz	A61B 17/90



FOREIGN PATENT DOCUMENTS						
Examiner Initials	Reference Number	Country Code	Document Number	Publication Date	Patentee or Applicant	Class/Subclass
	DR	WO	97/25942	Jul. 1997	Schwartz	A61F 2/32
	DS	WO	97/38676	Oct. 1997	Peterson et al.	A61K 9/10
	DT	WO	98/30617	Jul. 1998	Searle	C08G 63/12
	DU	WO	99/02654	Jan. 1999	Peterson et al.	A61L 27/00
	DV	WO	99/08728	Feb. 1999	Atkinson et al.	A61L 27/00
	DW	WO	99/47186	Sep. 1999	Suh et al.	A61L 27/00
	DX	WO	99/51719	Oct. 1999	Fofonoff et al.	C12N 3/00
	DY	WO	00/09179	Feb. 2000	Gianetti et al.	A61L 25/00
	DZ	WO	00/48550	Aug. 2000	Atkinson et al.	A61K
	EA	WO	00/59411	Oct. 2000	Fell et al.	A61F 2/38
	EB	WO	00/74554	Dec. 2000	Schwartz et al.	A61B
	EC	WO	01/17463	Mar. 2001	Mansmann	A61F 2/30
	ED	WO	01/19254	Mar. 2001	Cummings et al.	A61B 17/064
	EE	WO	01/35968	May 2001	Ashkar et al.	A61K 35/00
	EF	WO	01/45764	Jun. 2001	Muller et al.	A61L 27/36
	EG	WO	01/68800	Sep. 2001	Trustees of Columbia U., City of N.Y.	B39
	EH	WO	01/70142	Sep. 2001	Carigan et al.	A61F 2/38
	EI	WO	02/22014	Mar. 2002	Alexander et al.	A61B5/055
	EJ	WO	02/23483	Mar. 2002	Steines et al.	G06T 11/00
	EK	WO	02/34310	May 2002	Dickson et al.	A61L 31/04
	EL	WO	02/36147	May 2002	Liu et al.	A61K 38/16
	EM	WO	02/06268	Dec. 2002	Lang et al.	A61F
	EN	WO	03/007788	Jan. 2003	Prasanna et al.	A61F
	EO	WO	03/051210	Jun. 2003	Ek et al.	A61B 17/58
	EP	WO	04/043305	May 2004	Tsougarakis et al.	A61F 2/30

OTHER DOCUMENTS			
Examiner Initials	Reference Number	Author	Title of Article, Title of Journal, Volume Number, Page Numbers, Date
	EQ	Taha et al.	"Modeling and design of a custom made cranium implant for large skull reconstruction before a tumor removal", Phidias Newsletter No. 6, pages 3, 6, June 2001. Retrieved from the Internet: URL: <a href="http://www.materialise.com/medical/files/pdf">http://www.materialise.com/medical/files/pdf</a>
	ER	Kidder J. et al.	"3D model acquisition, design, planning and manufacturing of orthopaedic devices: a framework", Proceedings of the SPIE – Advanced Sensor and Control-System Interface, Boston, MA, Vol. 2911, pgs. 9-22, 21 November 1996
	ES	Carr J.C. et al.	"Surface Interpolation with Radial Basis Functions for Medical Imaging", IEEE Transactions on Medical Imaging, IEEE, Inc. New York, Vol. 16, No. 1, 1 February 1997, pgs. 96-107.
	ET	C.S. Ranawat et al.	"MacIntosh Hemiarthroplasty in Rheumatoid Knee" Acta Orthop Belg. 1973 Jan-Feb: 39(1):102-112
	EU	B. Blum et al.	"Knee Arthroplasty in Patients with Rheumatoid Arthritis", ANN. Rheum. Dis. 1974 Jan: 33(1):1-11
	EV	Nelson M.D. et al.	"Arthroplasty and Arthrodesis of the Knee Joint", Orthop. Clin. North Am. 1971 Mar: 2(1):245-64.
	EW	McCollum et al.	"Tibial Plateau Prosthesis in Arthroplasty of the Knee", J. Bone Joint Surg. Am. 1970 Jun:52(4):827-8.
	EX	Hastings D.E. et al.	"Double Hemiarthroplasty of the Knee in Rheumatoid Arthritis. A Survey of Fifty Consecutive Cases", J. Bone Joint Surg. Br. 1973 Feb:55(1):112-118.
	EY	Schron, D. et al.	"MacIntosh Arthroplasty in Rheumatoid Arthritis", Rheumatol Rehabil. 1978 Aug:17(3):155-163.
	EZ	McKeever, D.C. et al.	"The Classic Tibial Plateau Prosthesis", Clin. Orthop. Relat. Res. 1985 Jan-Feb:(192):3-12.
	FA	Conaty et al.	"Surgery of the Hip and Knee in Patients with Rheumatoid Arthritis", J. Bone Joint Surg. Am. 1973 Mar:55(2):301-314.

<b>OTHER DOCUMENTS (Continued)</b>			
	<b>FB</b>	<b>MacIntosh et al.</b>	<b>"The Use of the Hemiarthroplasty Prosthesis for Advanced Osteoarthritis and Rheumatoid Arthritis of the Knee", J. of Bone &amp; Joint Surg. 1972, Vol. 54B, No. 2, pgs. 244-255</b>
	<b>FC</b>	<b>MacIntosh</b>	<b>"Arthroplasty of the Knee in Rheumatoid Arthritis Using the Hemiarthroplasty Prosthesis", Synovectomy and Arthroplasty in Rheumatoid Arthritis pp. 79-80, Second Int'l. Symposium, Jan. 27-29, 1967 (Basle, Switzerland)</b>
	<b>FD</b>	<b>MacIntosh, D.L.</b>	<b>"Hemiarthroplasty of the Knee Using a Space Occupying Prosthesis for Painful Varus and Valgus Deformities", J. Bone Joint Surg. Am. 1958 Dec:40-A:1431.</b>
	<b>FE</b>	<b>Stauffer R. et al.</b>	<b>"The MacIntosh Prosthesis. Prospective Clinical and Gait Evaluation", Arch. Surg. 1975 Jun:110(6):717-720.</b>
	<b>FF</b>	<b>Clary BB et al.</b>	<b>"Experience with the MacIntosh Knee Prosthesis", South Med. J. 1972 Mar:65(3):265-272.</b>
	<b>FG</b>	<b>Ghelman MD, et al.</b>	<b>"Kinematics of the Knee After Prosthetic Replacements", Clin. Orthop. 1975 May: (108): 149-157.</b>
	<b>FH</b>	<b>Henderson, MD et al.</b>	<b>"Experience with the Use of the Macintosh Prosthesis in Knees of Patients with Rheumatoid Arthritis", South. Med. J. 1969 Nov:62(11):1311-1315.</b>
	<b>FI</b>	<b>Potter M.D.</b>	<b>"Arthroplasty of the Knee With Tibial Metallic Implants of the McKeever and MacIntosh Design", Sug. Clin. North Am. 1969 Aug:49(4):903-915.</b>
	<b>FJ</b>	<b>Potter T.A., et al.</b>	<b>"Arthroplasty of the Knee in Rheumatoid Arthritis and Osteoarthritis: A Follow-up Study After Implantation of the McKeever and MacIntosh Prostheses", J. Bone Joint Surg. Am. 1972 Jan:54(1):1-24.</b>
	<b>FK</b>	<b>Bogoch et al.</b>	<b>"Supracondylar Fractures of the Femur Adjacent to Resurfacing and MacIntosh Arthroplasties of the Knee in Patients with Rheumatoid Arthritis", Clin. Orthop. 1988 Apr. (229):213-220.</b>

OTHER DOCUMENTS (cont.)			
	FL	Cameron et al.	"Review of a Failed Knee Replacement and Some Observations on the Design of a Knee Resurfacing Prosthesis", Arch. Orthop Trauma Surg. 1980:97(2):87-89.
	FM	Kates A. et al.	"Experiences of Arthroplasty of the Rheumatoid Knee Using MacIntosh Prostheses", Ann. Rheum. Dis. 1969 May:28(3):328.
	FN	Jessop J.D. et al.	"Follow-up of the MacIntosh Arthroplasty of the Knee Joint", Rheumatol Phys. Med. 1972 Feb: 11 (5): 217-224.
	FO	Andersson GB et al.	"MacIntosh Arthroplasty In Rheumatoid Arthritis", Acta. Orthop. Scand. 1974:45 (2): 245-259
	FP	Wordsworth et al.	"MacIntosh Arthroplasty for the Rheumatoid Knee: A 10-year Follow Up", Ann. Rheum. Dis. 1985 Nov:44 (11): 738-741.
	FQ	Kay N.R. et al.	"MacIntosh Tibial Plateau Hemiprosthesis for the Rheumatoid Knee", J. Bone Joint Sur. Br. 1972 May: 54(2): 256-262.
	FR	Porter M.L. et al.	"MacIntosh Arthroplasty: a long-term review", J. R. Coll. Sur. Edinb. 1988 Jan-Feb: (192): 199-201.
	FS	Tamez-Pena, J. et al.	"MRI Isotropic Resolution Reconstruction from two Orthogonal Scans", Proceedings of the SPIE – The International Society for Optical Engineering SPIE-OMT. Vol. 4322, pp. 87-97, 2001.
	FT		International Search Report dated 23 February 2005
	FU		International Search Report dated 13 May 2005

Examiner Signature: \_\_\_\_\_

Date Considered: \_\_\_\_\_

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation *if not* in conformance and not considered. Include copy of this form with next communication to applicant.

**Section 6. Copies of Listed Information Items Accompanying This Statement**

*NOTE: 37 C.F.R. section 1.98(a)(2) requires that any information disclosure statement filed under section 1.97 shall include: "A legible copy of: (1) Each U.S. and foreign patent; (ii) Each publication or that portion which caused it to be listed; and (iii) All other information or that portion which caused it to be listed, except that no copy of a U.S. patent application need be included . . ."*

*NOTE: The wording in section 1.98(a)(2)(iii) makes it clear that the requirement to submit a copy of each item of information listed in an information disclosure statement does not apply to the citation of a U.S. patent application. Notice of January 9, 1992, 1135 O.G. 13-25, at 14.*

Legible copies of all items listed in Forms PTO/SB/08A and 08B (substitute for Form PTO-1449) accompany this information statement.

*(complete the following, if applicable)*

☒ Exception(s) to above:

☐ Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.

☐ Cumulative patents or publications identified in Section 5.

**U.S. patent citations are not included pursuant to the United State Patent and Trademarks Office's September 21, 2004 waiver of the copy requirement in 37 CFR 1.98 for cited pending U.S. patent citations when the patent citations are available in the USPTO's IFW system.**

**Section 7A. Concise Explanation of Non-English Language Listed Information Items—EPO Search Report**

The relevance with respect to the following citations listed on Forms PTO/SB/08A and 08B (substitute for PTO-1449):

is submitted on the basis of the accompanying:

*(check the appropriate item)*

☒ EPO search reports that are in the English language,

☐ EPO search report that is not in the English language and that is accompanied also by an English language version of the EPO search report,

that issued on the corresponding European patent application.

**Section 10. Identification of Person(s) Making This Information Disclosure Statement**

The person making this certification is

*(check each applicable item)*

- (a) ☐ the inventor(s) who signs below

\_\_\_\_\_  
**SIGNATURE OF INVENTOR**

\_\_\_\_\_  
*(type name of inventor who is signing)*

- (b) ☐ an individual associated with the filing and prosecution of this application (37 C.F.R. section 1.56(c))

\_\_\_\_\_  
**SIGNATURE OF INVENTOR**

\_\_\_\_\_  
*(type name of inventor who is signing)*

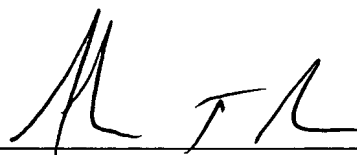
- (c) ☒ the practitioner who signs below on the basis of the information:

*(check each applicable item)*

☐ supplied by the inventor(s).

☐ supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. section 1.56(c)).

☒ in the practitioner's file.

  
\_\_\_\_\_  
**SIGNATURE OF PRACTITIONER**

Alexander J. Smolenski, Jr., Esq.  
*(type or print name of practitioner)*

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